

**National Organic Standards Board  
Materials and Handling Committees  
Discussion Document on the Definition of Materials**

**October 19, 2007**

**1. Problem Statement**

The National Organic Standards Board (NOSB) and the United States Department of Agriculture's (USDA) Accredited certifying agents (ACAs) often are confronted with decisions about the classification of materials according to current definitions under the National Organic Program (NOP) regulations. For both the NOSB and ACAs, this determination has significant impact on organic producers and processors. In some situations, the result of the determination impacts whether or not a product can be used in organic production. In other situations, the result determines how a retail product shall be labeled according to its ultimate organic content (as a "made with" or "organic" product).

Moreover, while many substances have agricultural origins, they may have been processed excessively to a point beyond which their agricultural nature continues to exist. Many ACAs and members of the NOSB believe that revisiting the current definitions of "agricultural inputs", "agricultural product", "ingredient", "nonagricultural substance", "nonsynthetic (natural)", "processing", and "synthetic" within the NOP regulations may help provide further clarity in making these decisions.

The purpose of this document is to allow the public to see the current work being done on this topic and elicit public comment on these issues to aid the Materials and Handling Committees (Joint Committee) of the NOSB in completing our work. This document is submitted for public comment in conjunction with a pair of graphical documents that are being developed to help clarify these decisions.

The Joint Committee recognizes that these issues also have potential impact in relation to certified organic production of crops and livestock. Comments with consideration of these issues in relation to these areas of production are encouraged.

The goal of this process is not to re-write the National List (NL). The NOSB expects that the document resulting from this process will confirm and support the vast majority of decisions made by prior boards.

**2. The National List of Allowed and Prohibited Substances**

The classification of certified organic products for retail is based on the level of inclusion of certified organic agricultural product ingredients ("100% organic", "organic", or "made with"). Nonorganic agricultural products to be used in certified "organic" products for human consumption must be listed on the NL §205.606. Nonsynthetic

nonagricultural substances in certified organic products for human consumption must be listed on the NL §205.605(a). Synthetic substances in certified organic products for human consumption must be on the NL §205.605(b). “Made with” products can contain non-organic agricultural products not included on NL §205.606. However, “made with” products can be affected by definitions of “agricultural products” and “nonagricultural substance”.

In crop production, nonsynthetic nonagricultural substances are allowed unless listed on the NL §205.602, while synthetic substances are prohibited unless listed on the NL §205.601.

In livestock production, nonsynthetic nonagricultural substances are allowed unless included on the NL §205.604, while synthetic substances are prohibited unless included on the NL §205.603.

### 3. Historical Perspective

#### 3.1 The Organic Food Production Act of 1990

The Organic Food Production Act (OFPA) was passed by Congress in 1990 and signed by the President. One of the three defined purposes of the act was “to establish national standards governing the marketing of certain agricultural products as organically produced products” (§2102(1)).

The act defines **Agricultural Products** as “*any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock that is marketing in the United States for human or livestock consumption*” (§2103(1)).

The act defines **Organically Produced** as “*an agricultural product that is produced and handled in accordance with this title*” (§2103 (14)).

**Synthetic** is defined as “*a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes*” (§2103 (21)).

The act defines **Processing** as a term meaning “*cooking, baking, heating, drying, mixing, grinding, churning, separating, extraction, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, or otherwise manufacturing, and included the packaging, canning, jarring, or otherwise enclosing food in a container*” (§2103 (17)).

OFPA did not define the terms “Agricultural”, “Nonagricultural”, or “Nonsynthetic”.

### 3.2 The National Organic Program and the National Organic Standards Board

Under the authority of OFPA, the National Organic Program (NOP) was formed within the USDA. The Secretary of Agriculture appointed the original members of the NOSB in 1993. By 1994, the NOSB was working to develop the NL, a list of approved and prohibited substances (§2103 (12)) for use in certified organic food production as directed according to OFPA. At that time, the NOSB introduced the distinction between “agricultural products” and “nonagricultural substances”.

### 3.3 The Final Rule

Final organic regulations, known as The Final Rule, were published in 2000.

The Final Rule defines **Nonagricultural substance** as “*a substance that is not a product of agriculture, such as a mineral or bacterial culture that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin that is extracted from, isolated from or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction*” (§205.2 Terms defined).

**Nonsynthetic (natural)** is defined as “*a substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502 (21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term used in the Act*” (§205.2 Terms defined).

The Final Rule does not specifically define “process” or “synthetic process” and it further clarifies the definition of **Processing** by adding *curing, slaughtering, distilling and chilling* to the definition (§205.2 Terms defined).

## 4. Discussion

### 4.1 Agricultural and Nonagricultural

The Joint Committee believes the definitions in the Final Rule for Agricultural product and Nonagricultural substances are inconsistent and do not provide clear guidelines for evaluating substances as an “agricultural product” versus a “nonagricultural substance”.

#### 4.1.1 Confusion caused by listing of specific examples

Gums are an example of this confusion. Gums, by the current definition of “nonagricultural substance” in §205.2, should not be considered agricultural or organic since gums are specifically listed as an example of a nonagricultural product in the definition. Yet, “gums-water extracted” are listed in §205.606(b). Compounding the problem, gums are available as certified organic products. This, by definition means that

they must be “agricultural products”. Pectins present a similar problem. They are specifically mentioned in the definition of “Nonagricultural substance”, yet “Pectin (high-methoxy)” is listed in §205.606(e).

The Joint Committee is considering the possibility of recommending a deletion of the definition of **Nonagricultural substance** or at least the examples within the definition.

#### 4.1.2 Recognizable or unrecognizable

Inconsistencies and confusion have continued because of the conflicts with the current definition of “Nonagricultural substance” regarding the statement that “*a nonagricultural ingredient also includes any substance, . . . that is extracted from, isolated from or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.*” Many processed agricultural products have been extracted, isolated, or fractionated during processing to the point where the product no longer resembles the starting agricultural product. Examples of organic products in potential conflict with the definition include, but not limited to, whey protein concentrate, milk protein concentrate, evaporated cane juice, and maltodextrin. It could be determined that all of these products are “extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate or fraction” and by definition could be determined not to be agricultural.

The inclusion in a definition that the extracted, isolated, or fractionated portion of an agricultural product must maintain a recognizable identity of the agricultural product seems problematic and confusing. While many methods of processing are specifically allowed, the strict enforcement of this part of the definition could mean that nearly every process beyond dehydration could result in a nonagricultural substance.

The direction taken by this definition is supportable. However, it is virtually impossible for an extracted, isolated, or fractionated item to remain recognizable with the agricultural product from which it originated. Also, whether a material is “recognizable” as its agricultural origin or not is a judgment that will continue to allow ambiguity within the regulation.

### 4.2 The Agricultural to Synthetic continuum

#### 4.2.1 Agricultural versus Nonagricultural and Synthetic versus Nonsynthetic

##### 4.2.1.1 The old paradigm

Historically, where ever this question has been addressed it has been viewed as two separate entities. There was the question of “agricultural” versus “nonagricultural” and “synthetic” versus “nonsynthetic”. They were always addressed as separate issues. As a result, confusion developed as to the degree of processing that an “agricultural product”

could undergo to become “nonagricultural” versus the amount of processing for part of it to become “synthetic”.

#### 4.2.1.2 The new paradigm

At this time, the Joint Committee believes that these two questions should be viewed as one continuum. Agricultural products can be minimally processed to nonagricultural substances, and further processed to synthetic substances. Cellulose is an example of this type of substance as listed in §205.605(b).

#### 4.2.1.3 Agricultural to Synthetic

Under this newly proposed continuum, there are two major determinations to be made. The first consideration is whether the substance is an agricultural product. Thus far, the Joint Committee has tried to isolate the intermediate steps to answer this larger question from the definition of **Agricultural product** as defined in the OFPA. The Joint Committee is interested in public comment and inputs to help define these intermediate steps.

The second determination is whether a substance that has been determined to “not be an agricultural product”, is synthetic or not. The Joint Committee believes the intermediate steps to answer this large question will come from the definitions of synthetic, nonagricultural substance, Nonsynthetic (natural), and Processing. The Joint Committee has not had time to continue through this part of the process to a satisfactory extent and welcomes public input and comment on this matter.

### 4.3 Synthetic versus Nonagricultural-nonsynthetic

#### 4.3.1 Chemical change and separation

The OFPA defines **synthetic** as a substance “*formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring*” ... source. The Joint Committee notes that this is a definition from OFPA and cannot be changed. However, the Joint Committee finds the two parts of this definition confusing. The first part seems to include all chemical processes. The second part of the definition seems to include only the chemical change where newly created substance[s] are then extracted from the naturally occurring source.

Further review of this definition could yield a determination that the first mention of “chemical process” in the definition of synthetic refers to chemical processes between synthetic substances. Thus substances resulting from chemical changes between synthetic substances would be considered synthetic.

The mention of “*a process that chemically changes a substance extracted from a naturally occurring . . . source*” could be considered specific to chemical changes occurring in Agricultural or Nonsynthetic (natural) substances where the extracted

portion is determined to be synthetic. If the chemical change and extraction were the only determination of an agricultural product yielding a synthetic substance, then items such as egg white lysozyme, which is currently listed on §205.605(a), should be considered synthetic. The Joint Committee welcomes public comment examining this matter.

The OFPA further includes in the definition of **synthetic** that “*the term shall not apply to substances created by naturally occurring biological processes*”. Under the old paradigm of agricultural versus nonagricultural and synthetic versus nonsynthetic, this would seem to indicate that a substance created by naturally occurring biological processes would be determined to be nonagricultural. However, the reference to “naturally occurring biological processes” is only stating that the substance is not synthetic. It is not determining that it is “agricultural” or “nonagricultural-nonsynthetic”. Therefore, substances created by naturally occurring biological processes originating from agricultural products can maintain their classification as an agricultural product. This determination is, of course, assuming that the confusion created by the “unrecognizable” clause currently in the definition of Nonagricultural substance is resolved. The Joint Committee welcomes public comment and input on this entire matter.

The Final Rule defines **Nonsynthetic (natural)** as a natural substance that does not undergo a “*synthetic process*”. A specific definition of “synthetic process” has not been established. The Joint Committee has considered whether this is an allowed process that involves a synthetic substance in the chemical process or if it includes other processes not included in the definition of Processing. The Joint Committee welcomes public comment and input on this part of the discussion.

#### 4.4 Not all life is Agricultural

The rule is fairly clear that not all life is considered agricultural. “Bacterial cultures” are specifically included in the definition of Nonagricultural substance. Dairy cultures and yeast are currently listed on 605(a). Petitions have been filed with the NOP to move yeast from 605(a) to 606. The NOSB has considered this matter as recently as March 2007. At that time, the Handling committee had recommended not making that change in the NL. The petition was pulled from consideration by the petitioner prior to a final vote being taken on the matter by the NOSB.

In the past, public comment has focused on the impact of identifying yeast as an agricultural product and how this would impact the feeding of livestock as yeast is often included in the diet of livestock. If yeast were identified as an agricultural product then all yeast fed to livestock would be required to be certified organic. The NOSB recognizes the similarity between yeast and mushrooms, which are currently considered agricultural and being certified as organic, but notes that there are significant differences also. Continued public comment on this matter is welcome.

## **5. Conclusion**

The Joint Committee and entire NOSB are publishing these documents regarding the Definition of Materials to notify the industry and the public that we are aware of the problems that are being experienced in the industry. Various NOSB committees have debated these issues since the formation of the NOSB. At this time, we have not resolved all these issues. Our desire with the publication of these documents is to update the industry and the public as to our progress thus far and to generate comments. Since we have not completed our consideration of all potential issues that could be affected by a document with such a wide-scope, it is possible that we have not realized all areas that could be causing confusion. Public comment on those areas is welcome also.

The adjoining document includes two separate documents. The first is a graphic of “the universe of materials” and the second is a decision tree regarding the classification of materials that is still under development. The public is encouraged to examine and comment on both of these documents. The public is specifically encouraged to take specific substances through the decision tree. Comments regarding the portion of the decision tree that has been developed thus far as well as recommendations to help complete additional sections of the tree are welcome and encouraged.

Finally, the Joint Committee is fairly convinced that this matter should not be taken up piecemeal. Since each single issue has a wide range of implications, it seems imperative that the entire Definition and Classification of Materials issue be examined in its entirety. We realize that this mode of action could delay the ultimate publishing of a final document and delay a resolution of any of the individual issues discussed here. We apologize to the industry for this delay but we believe that this is the best course of action. In order to set a policy that will best serve the industry, the Joint Committee is deliberating over these very important details. This process is taking more time than most recommendations. We thank the industry for its patience during this process.

# The “Universe” of Materials

## Everything else is Non-Agricultural, Non-Synthetic

(Not Allowed for Handling and Allowed for  
Crops / Livestock)

Definition of Non-Agricultural Substance from Final Rule = “A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.”

### Agricultural Products

Agricultural Product (OFPA) = “Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock that is marketed in the US for human or livestock consumption.”

Processing (OFPA) = “Cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, or otherwise manufacturing, and includes the packaging, canning, jarring, or otherwise enclosing food in a container.”  
(Final Rule also includes) = “Curing, slaughtering, distilling, chilling.”

#### § 205.606

Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

### Synthetic

Synthetic (OFPA) = “A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.”

#### § 205.601

Allowed for  
crops

#### § 205.603

Allowed for  
livestock

#### § 205.605(b)

Allowed for  
handling

§ 205.602 and  
§ 205.604  
Prohibited Non-  
Synthetic  
in Crops &  
Livestock

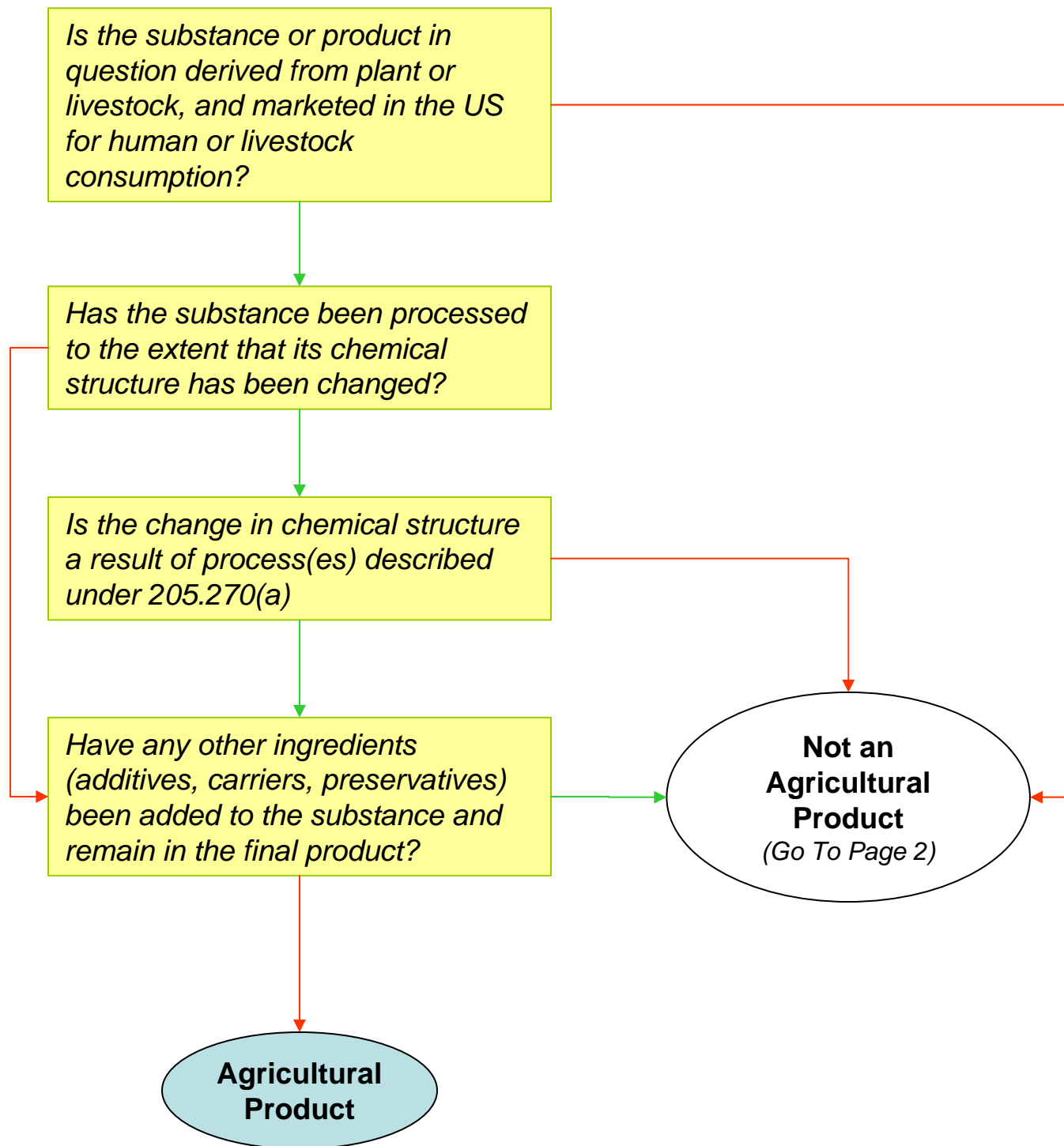
§ 205.605(a)  
Non-Synthetic  
Allowed  
No OFPA Definition

October 19, 2007



# Definition of Materials Decision Tree

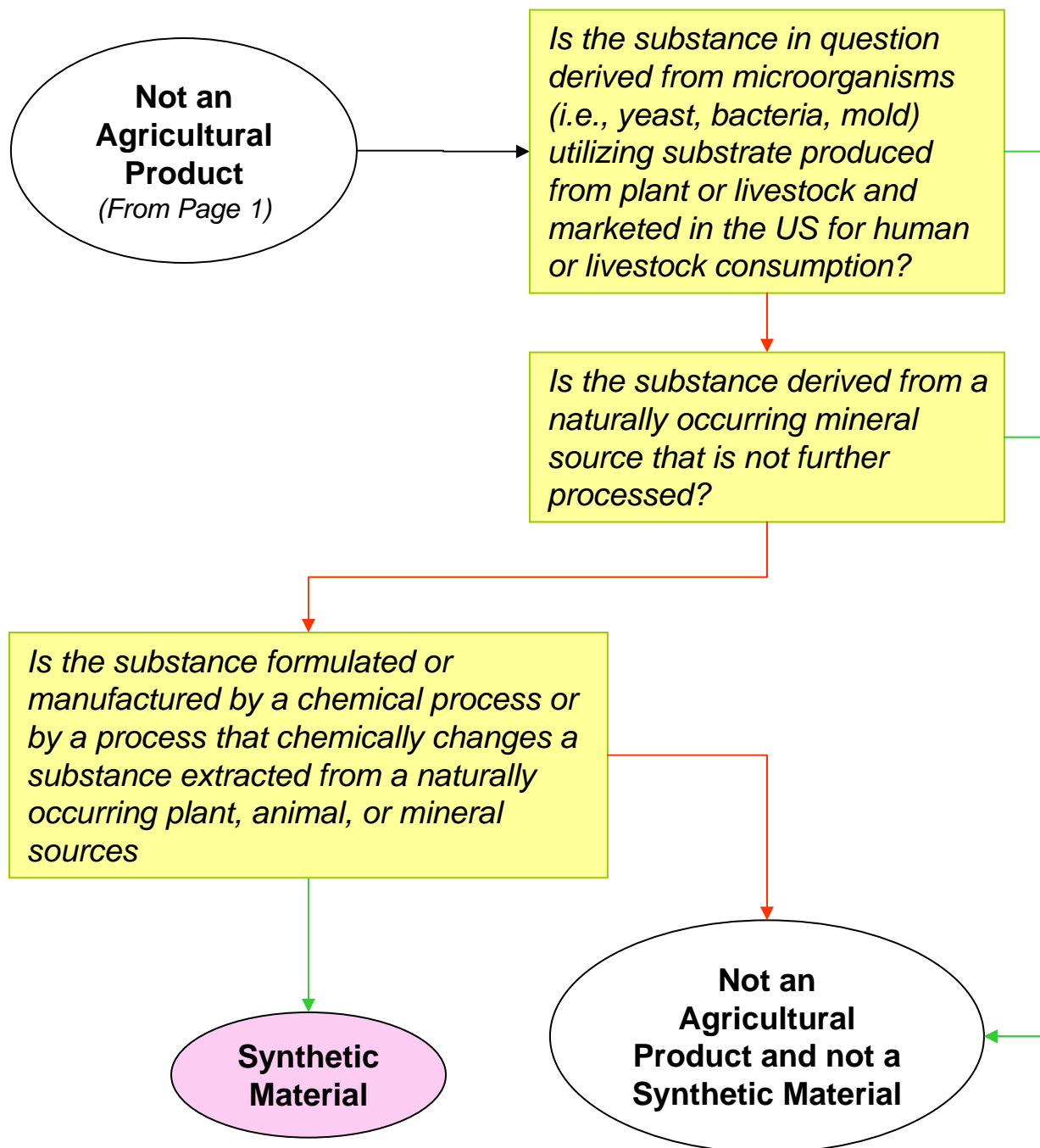
Page 1



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# Definition of Materials Decision Tree

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Green Arrow = Yes, Red Arrow = No, Black Arrow = Proceed to Next Step